



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to: CFN 1121909

Public Health Service

Food and Drug Administration
Baltimore District Office
Central Region
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Baltimore, MD 21201-2199
Telephone: (410) 962-3396
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01-BLT-22

March 13, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph R. Daniels, President
Wanchese Fish Company, Inc.
Mill Landing Road
Wanchese, North Carolina 27981

Dear Mr. Daniels:

During a Food and Drug Administration inspection of your seafood processing and wholesale fish facility located at 48 Water Street, Hampton, Virginia, conducted February 21, 2001, our investigator observed a serious deviation from the Seafood HACCP regulations (Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)). This deviation causes your fresh blue fish to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

The deviation was as follows:

1. You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). Your firm did not follow the monitoring procedures of inspecting the blue fish for the presence of ice and/or take the internal temperature of the blue fish at the receipt critical control point to control histamine formation listed in your HACCP plan for scombroid species fish.
2. You must monitor the critical control points and implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). Your firm did not document that you inspected each lot of blue fish for the presence of ice and/or take the internal temperature of each lot of blue fish at the receipt critical control point to control the food safety hazard of histamine formation listed in your HACCP plan for scombroid species fish.
3. You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). Your monitoring procedures at the receipt critical control point are not adequate to control histamine formation in scombroid species fish. For example, your procedure requires that the "internal temperature of fish" is monitored by the "visual observation of adequacy of ice" and/or by the "transit temperature checks of every lot received", neither of which can determine the internal temperature of the fish.

We may take further action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

Mr. Joseph R. Daniels

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Please respond in writing within 15 working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response a copy of your HACCP plan to control histamines, receiving temperature monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations (21 CFR 123), and the food GMPs (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, at 10710 Midlothian Turnpike, Suite 424, Richmond, VA 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire may be reached at 804-379-1627, extension 14.

Sincerely,



Lee Bowers
Director, Baltimore District

cc: Virginia Department of Agriculture
and Consumer Services
Division of Consumer Protection
Office of Dairy and Food
1100 Bank Street, Suite 510
Richmond, Virginia 23219

Mr. Samuel C. Daniels
Secretary/Treasurer
Wanchese Fish Co., Inc.
48 Water Street
Hampton, Virginia 23663